U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute	for form 1449A/PTO			Complete if Known		
INEO	RMATION I	Meci	OCUDE	Application Number	10/532,291	
				Filing Date	October 21, 2003	
STAT	STATEMENT BY APPLICANT		First Named Inventor	Rodney William Kelly		
1	(use as many sheets a	s necessa	רצי)	Art Unit	To Be Assigned	
				Examiner Name	To Be Assigned	
Sheet	1	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)	

			U.S. PATENT DO	CUMENTS	
Examiner Initials	Cite No.1	U.S. Patent Document Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US-4,034,087	07/05/1977	Voorhees	
	2	US-4,127,612	11/28/1978	Kluender et al.	
	3	US-5,229,496	07/20/1993	Deeley et al.	
	4	US-5,391,485	02/21/1995	Deeley et al.	
	5	US-5,393,870	02/28/1995	Deeley et al.	
	6	US-5,602,007	02/11/1997	Dunn et al.	
	7	US-5,891,432	04/06/1999	Hoo	
	8	US-5,908,829	06/01/1999	Kelly	
	9	US-6,010,905	01/04/2000	Cohen et al.	
	10	US-6,127,378	10/03/2000	Gutterer	
	11	US-6,280,718 B1	08/28/2001	Kaufman et al.	
	12	US-6,458,585 B1	10/01/2002	Vachula et al.	
	13	US-6,458,589 B1	10/01/2002	Rambhatla et al.	

		F(REIGN PATENT I	DOCUMENTS	·	_	_
Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T*	
		Country Code ³ Number ⁴ (if known)	MM-DD-1111		rigures Appear	10	
	14	DE 100 64 991 A1	06/27/2002	Volker		X	_
	15	DE 24 31 558	01/23/1975	Kuehl jun et al.		X	_
	16	EP 0 269 017 B1	07/29/1992	Zimmermann et al.			
	17	EP 1 097 922 A1	05/09/2001	Maruyama et al.			
	18	EP 1 114 816 A1	07/11/2001	Maruyama et al.			
	19	EP 1 199 074 A1	04/24/2002	Moulon et al.			
	20	JP 10-29942	02/03/1998	Tadahiro et al.		X	
	21	WO 00/64260	11/02/2000	Benoit et al.			_
	22	WO 01/17479 A2	03/15/2001	Neal			•
	23	WO 02/092064 A2	11/21/2002	Kelly			_
	24	WO 91/06571	05/16/1991	Gefter et al.			_
	25	WO 92/08474	05/29/1992	Kay et al.			
	26	WO 94/24281	10/27/1994	Garman et al.			_
	27	WO 96/30022	10/03/1996	Desai et al.			_
	28	WO 99/12563	03/18/1999	Berzofsky et al.	1		

Examiner Signature	/Prema Mertz/	Date Considered	04/17/2008

^{*}EXAMINER- Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

As Assistance to the control of the property of the control of the property of the control of the property of

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Ur	ider the Paperwork Redu	iction Act	of 1995, no persons	are required to respond to a collection of	nformation unless it contains a valid QMB control number	
Substitute	ubstitute for form 1449BPTO NFORMATION DISCLOSURE TATEMENT BY APPLICANT (1456 as many sheets as necessary)		Complete if Known			
INFO	DMATIONI	NICCI	OSLIDE	Application Number	10/532,291	
				Filing Date	October 21, 2003	
SIAI	stitute for form 1449BPTO FORMATION DISCLOSURE ATEMENT BY APPLICANT (iute as many alreets as necessary) tt 2 of 9				First Named Inventor	Rodney William Kelly
Substitute for form 1449DPTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 2 of 9	iry)	Group Art Unit	To Be Assigned			
				Examiner Name	To Be Assigned	
Sheet	2	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)	

Cite Include runne of the author (in CAPITAL LITERS), title of the aricle (velves appropriate), title of the item (book, magazine, journal, serial, spragionia, eatable, exc., date, page(s), volume-issue number(s), publisher, city and/or country where published. 29				
	Cite No.1	item (book, magazine, journal, serial, symposium, catalog, etc.)., date, page(s), volume-issue number(s),	T ²	
	29	"Leukine®," Package Insert, Approved Text (February 1998)		
	30	Bulletin on the Rheumatic Diseases 51(2):1-7 (Retrieved from the internet at		
	31	Pentoxifylline in a Patient with Dermatomyositis," Ryumachi 37(5):719-726 (1997)		
	32			
	33	monophosphate in the Mechanisms by Which Prostaglandins Influence Human Sperm		
	34			
	35	Selectin on Human Neutrophils and Eosinophils by the Type IV Selective PDE Inhibitor,		
	36			
	37			
	38	BUCHSEL et al., "Granulocyte Macrophage Colony-Stimulating Factor: Current Practice and Novel Approaches," Clin. J. Oncol. Nurs. 6(4):198-205 (2002)		
	39	BUG et al., "cAMP Analogues Downregulate the Expression of Granulocyte Macrophage Colony-Stimulating Factor (GM-CSF) in Human Bone Marrow Stromal Cells In Vitro," Mediators of Inflammation 7:195-1999 (1998)		
	40	BURZYN et al., "Decrease in cAMP Levels Modulates Adhesion to Fibronectin and Immunostimulatory Ability of Human Dendritic Cells," <i>J. Leukoc. Biol.</i> 72:93-100 (2002)		

Examiner	/Prema Mertz/	Date	04/17/2008
Signature		Considered	

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DePARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless (contains a valid OMB control number.)

Substitute	for form 1449B/PTO				Complete if Known
INFO	INFORMATION DISCLOSURE			Application Number	10/532,291
	STATEMENT BY APPLICANT		Filing Date	October 21, 2003	
		First Named Inventor	Rodney William Kelly		
	(use as many sheets a	s necessa	אניו	Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	3	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	41	CANTRELL et al., "Cloning, Sequence, and Expression of a Human Granulocyte/Macrophage Colony-Stimulating Factor," <i>Proc. Natl. Acad. Sci. USA</i> 82(18):6250-6254 (1985)	
	42	CLAESSEN et al., "Reversal of Mucosal Tolerance by Subcutaneous Administration of Interleukin-12 at the Site of Attempted Sensitization," Immunology 88(3):363-367 (1996)	
	43	CROCKER et al., "Phosphodiesterase Type 4 Inhibitors, But Not Glucocorticoids, Are More Potent in Suppression of Cytokine Secretion by Mononuclear Cells from Atopic Than Nonatopic Donors," <i>J. Allergy Clin. Immunol.</i> 102(5):797-804 (1998)	
	44	DIECKGRAEFE & KORZENIK, "Treatment of Active Crohn's Disease with Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor," The Lancet 360:1478-1480 (2002)	
	45	DONCKIER et al., "IL-12 Prevents Neonatal Induction of Transplantation Tolerance in Mice," Eur. J. Immunol. 28(4):1426-1430 (1998)	
	46	DOUSA, T.P., "Cyclic-3', 5'-Nucleotide Phosphodiesterase Isozymes in Cell Biology and Pathophysiology of the Kidney," Kidney International 55:29-62 (1999)	
	47	DRUKKER et al., "Characterization of the Expression of MHC Proteins in Human Embryonic Stem Cells," Proc. Natl. Acad. Sci. USA 99(15):9864-9869 (2002)	
	48	DUNN et al., "IL-15 Regulation in Human Endometrial Stromal Cells," J. Clin. Endocrinol. Metab. 87(4):1898-1901 (2002)	
	49	ESCOFIER et al., "Effects of Interleukin-10 and Modulators of Cyclic AMP Formation on Endotoxin-Induced Inflammation in Rat Lung," Fundam. Clin., Pharmacol. 13(1):96-101 (1999)	
	50	GASPAR ELSAS et al., "Murine Myeloid Progenitor Responses to GM-CSF and Eosinophil Precursor Responses to IL-5 Represent Distinct Targets for Downmodulation by Prostaglandin E ₂ ," Br. J. Pharmacol. 130(6):1362-1368 (2000)	
	51	GENBANK ACCESSION NO. NM_000758 (2002)	
	52	GOERDT et al., "Other Functions, Other Genes: Alternative Activation of Antigen- Presenting Cells," Immunity 10:137-142 (1999)	

Examiner Signature	/Prema Mertz/	Date Considered	04/17/2008

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Pateni and Trademark Office: U.S. DEPARTMENT OF COMMERCE

	for form 1449B/PTO	iction Act	or 1993, no persons		of information unless it contains a valid OMB control number. Complete if Known
INFO	DMATIONIC	vieci	OCUPE	Application Number	10/532,291
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT			Filing Date	October 21, 2003
		First Named Inventor	Rodney William Kelly		
	(use as many sheets a	s necessa	(ערש	Group Art Unit	To Be Assigned
i				Examiner Name	To Be Assigned
Sheet	4	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)

Examiner	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the	T2
nitials	No.1	item (book, magazine, journal, serial, symposium, etalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	53	GROUX et al., "Interleukin-10 Induces a Long-Term Antigen-Specific Anergic State in Human CD4* T Cells," <i>J. Exp. Med.</i> 184:19-29 (1996)	
	54	GROUX et al., "A CD4*T-Cell Subset Inhibits Antigen-Specific T-Cell Responses and Prevents Colitis," Nature 389:737-742 (1997)	
	55	HAMILTON, J.A., "GM-CSF in Inflammation and Autoimmunity," Trends Immunol. 23(8):403-408 (2002)	
	56	HANCOCK et al., "Recombinant Granulocyte-Macrophage Colony-Stimulating Factor Down-Regulates Expression of IL-2 Receptor on Human Mononuclear Phagocytes by Induction of Prostaglandine," J. Immunol. 140(9):3021-3025 (1988)	
	57	HANIFIN & CHAN, "Monocyte Phosphodiesterase Abnormalities and Dysregulation of Lymphocyte Function in Atopic Dermatitis," J. Invest. Dermatol. 105:84S-88S (1995)	
	58	HANIFIN et al., "Type 4 Phosphodiesterase Inhibitors Have Clinical and In Vitro Anti- Inflammatory Effects in Atopic Dermatitis," Journal of Investigative Dermatology 107:51-56 (1996)	
	59	HARIZI et al., "Cyclooxygenase-2-Issued Prostaglandin E ₂ Enhances the Production of Endogenous IL-10, Which Down-Regulates Dendritic Cell Functions," <i>J. Immunol.</i> 168(5):2255-2263 (2002)	
*	60	HASKÓ et al., "Suppression of IL-12 Production by Phosphodiesterase Inhibition in Murine Endotoxemia is IL-10 Independent," Eur. J. Immunol. 28:468-472 (1998)	
	61	HATA et al., "Granulysin Blocks Replication of Varicella-Zoster Virus and Triggers Apoptosis of Infected Cells," Viral Immunol. 14(2):125-133 (2001)	
	62	HAYASHIDA et al., "Antiinflammatory Effects of Colforsin Daropate Hydrochloride, a Novel Water-Soluble Forskolin Derivative," <i>Ann. Thoracic Surgery</i> 71:1931-1938 (2001)	
	63	HOLT et al., "MHC Class II Antigen-Bearing Dendritic Cells in Pulmonary Tissues of the Rat," J. Exp. Med. 167:262-274 (1988)	
	64	ICHIMURA et al., "Differentiation of a Cell Line of Human Cervical Argyrophil Small Cell Carcinoma to Macrophage Lineage Cells," <i>Ipn. J. Cancer Res.</i> 90:523-529 (1999)	

Examiner Signature	/Prema Mertz/	Date Considered	04/17/2008

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Approved for usc through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449B/PTO 10/532.291 Application Number INFORMATION DISCLOSURE Filing Date October 21, 2003 STATEMENT BY APPLICANT First Named Inventor Rodney William Kelly (use as many sheets as necessary) To Be Assigned Group Art Unit Examiner Name To Be Assigned Sheet Attorney Docket Number 20747/280 (ARDBW/P29385US)

Examiner	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the	m2
Initials	No.1	itemocrame of the annual control of the control of	T ²
	65	KALIŃŚKI et al., "Dendritic Cells, Obtained from Peripheral Blood Precursors in the Presence of PGE ₂ , Promote Th2 Responses," Adv. Exp. Med. Biol. 416:363-367 (1997)	
	66	KALINSKI et al., "Final Maturation of Dendritic Cells Is Associated with Impaired Responsiveness to IrN-y and to Bacterial IL-12 Inducers: Decreased Ability of Mature Dendritic Cells to Produce IL-12 During the Interaction with Th Cells," <i>J. Immunol.</i> 162:3231-3236 (1999)	
	67	KALINSKI et al., "Prostaglandin E ₂ Induces the Final Maturation of IL-12-Deficient CDIa" CDB3" Dendritic Cells: The Levels of IL-12 Are Determined During the Final Dendritic Cell Maturation and Are Resistant to Further Modulation," J. Immunol. 161:2804-2809 (1998)	
	68	KAMBAYASHI et al., "Cyclic Nucleotide Phosphodiesterase Type IV Participates in the Regulation of IL-10 and in the Subsequent Inhibition of TNF-a and IL-6 Release by Endotoxin-Stimulated Macrophages," Journal of Immunology 155:4909-4916 (1995)	
	69	KANAMORI et al., "Migration of Neutrophils from Blood to Tissue: Alteration of Modulatory Effects of Prostanoid on Superoxide Generation in Rabbits and Humans," Life Science 60(16):1407-1417 (1997)	
	70	KANDA & WATANABE, "Ganglioside GD1a Enhances Immunoglobulin Production by Human Peripheral Blood Mononuclear Cells," Exp. Hematol. 28(6):672-679 (2000)	
	71	KELLY & CRITCHLEY, "Immunomodulation by Human Seminal Plasma: A Benefit for Spermatozoon and Pathogen?" Human Reproduction 12(10):220-2207 (1997)	
	72	KELLY et al., "Inflammatory Mediators and Endometrial Function—Focus on the Perivascular Cell," J. Reprod. Immunol. 57(1-2):81-93 (2002)	
	73	KELLY, J., "Shooting for the Moon: Bolstered By a New Research Agenda, Parkinson's Disease Researchers Aim High," Neurology Reviews.com 9(7):1-10 (2001)	
	74	KELLY et al., "The Immunosuppressive Contribution of Prostaglandin Components of Human Semen and Their Ability to Elevate Cyclic Adenosine Monophosphate Levels in Peripheral Blood Mononuclear Cells," J. Reprod. Immunol. 26:31-40 (1994)	
	75	KOELMAN et al., "Correlation Between Oral Sex and a Low Incidence of Precclampsia: A Role for Soluble HLA in Seminal Fluid?" <i>J. Reproductive Immunol.</i> 46:155-166 (2000)	

Signature	/Frema wenz/	Considered	04/17/2008
	ER: Initial if reference considered, whether or not citation is in conformant ince and not considered. Include copy of this form with next communication		aw line through citation if not

Date

Examiner

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

U	Order the raperwork Reduction Act of 1993, no persons are required to respond to a conection of information unless it contains a valid Owlo control infinite.								
Substitute	for form 1449B/PTO			Complete if Known					
INFO	DMATION	nec1	OSUDE	Application Number	10/532,291				
INFORMATION DISCLOSURE				Filing Date	October 21, 2003				
STATEMENT BY APPLICANT				First Named Inventor	Rodney William Kelly				
	(use as many sheets a	s necessa	iry)	Group Art Unit	To Be Assigned				
				Examiner Name	To Be Assigned				
Sheet	6	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)				

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-istue number(s), publisher, city and/or country where published.	T³
	76	KRENSKY, A.M., "A Novel Antimicrobial Peptide of Cytolytic T Lymphocytes and Natural Killer Cells," <i>Biochem. Pharmacol.</i> 59(4):317-320 (2000)	
	77	LECHNER et al., "Nestin-Positive Progenitor Cells Derived from Adult Human Pancreatic Islets of Langerhans Contain Side Population (SP) Cells Defined by Expression of the ABCG2 (BCRP1) ATP-Binding Cassette Transporter," Biochem. Biophys. Res. Comm. 293:670-674 (2002)	
	78	LEE et al., "Isolation of cDNA for a Human Granulocyte-Macrophage Colony- Stimulating Factor by Functional Expression in Mammalian Cells," <i>Proc. Natl. Acad. Sci.</i> USA 82:4360-4364 (1985)	
	79	LOUIS et al., "Decrease in Systemic Tolerance to Fed Ovalbumin in Indomethacin- Treated Mice," International Archives of Allergy and Immunology 109(1):21-26 (1996)	
	80	MAIER et al., "Unique Molecular Surface Features of in vivo Tolerized T Cells," Proc. Natl. Acad. Sci. USA 95:4499-4503 (1998)	
	81	MAURANO et al., "Intranasal Administration of One Alpha Gliadin Can Downregulate the Immune Response to Whole Gliadin in Mice," Scand. J. Immunol. 53:290-295 (2001)	
	82	MIYATAKE et al., "Structure of the Chromosomal Gene for Granulocyte-Macrophage Colony Stimulating Factor: Comparison of the Mouse and Human Genes," <i>EMBO J.</i> 4(10):2561-2568 (1985)	
	83	MORIUCHI et al., "Synergistic Inhibition of Pannus Tissue Development In Vitro by PGE1 Plus Phosphodiesterase 4 Inhibitors," Arthritis and Rheumatism 41(9):S161 (1998)	
	84	MÜLLER et al., "IL-12 as Mediator and Adjuvant for the Induction of Contact Sensitivity In Vivo," <i>J. Immunol.</i> 155(10):4661-4668 (1995)	
	85	MÜLLER et al., "Subtypes of the Type 4 cAMP Phosphodiesterases: Structure, Regulation and Selective Inhibition," <i>Trends Pharmacol. Sci.</i> 17:294-298 (1996)	
	86	NÉMETH et al., "Amrinone and Theophylline Differentially Regulate Cytokine and Nitric Oxide Production in Endotoxemic Mice," Shock 7(5):371-375 (1997)	
	87	NEWBERRY et al., "Cyclooxygenase-2-Dependent Arachidonic Acid Metabolites Are Essential Modulators of the Intestinal Immune Response to Dietary Antigen," <i>Nature</i> Medicine 5(8):900-906 (1999)	

Examiner Signature	/Prema Mertz/	Date Considered	04/17/2008

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not ¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

in conformance and not considered. Include copy of this form with next communication to applicant.

	Ur	Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.										
	. Substitute	for form 1449B/PTO			Complete if Known							
ļ	INFO	RMATION I) Sec	OSUDE	Application Number	10/532,291						
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	October 21, 2003						
					First Named Inventor	Rodney William Kelly						
		(use as many sheets o	is necesso	ury)	Group Art Unit	To Be Assigned						
					Examiner Name	To Be Assigned						
Sheet 7 of 9		Attorney Docket Number	20747/280 (ARDBW/P29385US)									

Examiner	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the	T2
Initials	No.1	item (book, magazine, journal, scrial, symposium, eatalog, etc.)., date, page(s), volume-issue number(s), publisher, city and/or country where published.	Ľ
	88	NEWBERRY et al., "Spontaneous and Continuous Cyclooxygenase-2-Dependent	
	l	Prostaglandin E2 Production by Stromal Cells in the Murine Small Intestine Lamina	
		Propria: Directing the Tone of the Intestinal Immune Response," <i>J. Immunol.</i> 166(7):4465-4472 (2001)	İ
	89		-
		NINNEMANN, J.L., "Monocytes and Macrophages," in Prostaglandins, Leukotrienes, and the Immune Response, Chapter 3, pp.34-52 (1988)	
	90	OCHOA et al., "T-Cell Release of Granulysin Contributes to Host Defense in Leprosy," Nature Medicine 7(2):174-179 (2001)	
	91	PALFREYMAN & SOUNESS, "Phosphodiesterase Type IV Inhibitors," Progress in Medicinal Chemistry 33:1-52 (1996)	
	92	PFENDLER & KAWASE et al., "The Potential of Stem Cells," Obstetrical & Gynecology Survey 58(3):197-208 (2003)	
	93	PIQUET-PELLORCE et al., "Prostaglandin E2 Potentiates Granulocyte-Macrophage	1
		Colony Stimulating Factor-Induced Histamine Synthesis in Bone Marrow Cells: Role of cAMP," Life Sciences 48(25):2377-2385 (1991)	
	94	RIESER et al., "Prostaglandin E2 and Tumor Necrosis Factor α Cooperate to Activate	
		Human Dendritic Cells: Synergistic Activation of Interleukin 12 Production," J. Exp. Med. 186(9):1603-1608 (1997)	
	95	RITZ et al., "On the Generation of Allergic Airway Diseases: From GM-CSF to Kyoto," Trends Immunol. 23(8):396-402 (2002)	
	96	ROBERTSON & SHARKEY, "The Role of Semen in Induction of Maternal Immune Tolerance to Pregnancy," Seminars in Immunology 13:243-254 (2001)	
	.97	ROBERTSON et al., "Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF)	
		Targets Myeloid Leukocytes in the Uterus During the Post-Mating Inflammatory Response in Mice," J. Reproductive Immunology 46:131-154 (2000)	
	98	ROWE et al., "Inability of Histamine to Regulate TNF-α Production by Human Alveolar Macrophages," Am. J. Respir. Cell Mol. Biol. 17:218-226 (1997)	
	99		+
	""	ROZENGURT et al., "Mitogenic Effect of Prostaglandin E ₁ in Swiss 3T3 Cells: Role of Cyclic AMP," Journal of Cellular Physiology 116:379-384 (1983)	

Examiner Signature	/Prema Mertz/	Date Considered	04/17/2008

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/3 1/2002. OMB 0651-0031

U.S. Patent and Tandemark Office: U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Tandemark Office: U.S. DEPARTMENT OF COMMERCE

Under the Pancework Behavior Act of 1995, no persons are pressived to respond to a collection of information unless it contains a value of the control university.

Substitute	for form 1449B/PTO			Complete if Known		
INFO	DMATIONE	Tec:	OCUDE	Application Number	10/532,291	
INFORMATION DISCLOSURE				Filing Date	October 21, 2003	
SIAI	STATEMENT BY APPLICANT			First Named Inventor	Rodney William Kelly	
	(use as many sheets a	s necesso	iry)	Group Art Unit	To Be Assigned	
				Examiner Name	To Be Assigned	
Sheet	8	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	heclude name of the author (in CAPITAL LETTERS), title of the artisle (when appropriate), title of the item (book, magazine, journal, serial, symposium, eatloge, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	100	RUGTVEIT et al., "Differential Distribution of B7.1 (CD80) and B7.2 (CD86) Costimulatory Molecules on Mucosal Macrophage Subsets in Human Inflammatory Bowel Disease (IBD)," Clin. Exp. Immunol. 110(1):104-113(1997)	
	101	SALMI & JALKANEN et al., "Human Leukocyte Subpopulations from Inflamed Gut Bind to Joint Vasculature Using Distinct Sets of Adhesion Molecules," <i>Journal of Immunology</i> 166(7):4650-4657 (2001)	
	102	SANTAMARIA et al., "Rolipram Inhibits Staphylococcal Enterotoxin B-Mediated Induction of the Human Skin-Homing Receptor on T Lymphocytes," J. Invest. Dermatol. 113:82-89 (1999)	
	103	SCHEUER et al., "Interference with Tolerance Induction in Vivo by Inhibitors of Prostaglandin Synthesis," Cellular Immunology 104(2):409-418 (1987)	
	104	SCHWACHA et al., "Cyclooxygenase 2-Mediated Suppression of Macrophage Interleukin-12 Production After Thermal Injury," Am. J. Physiol. Cell Physiol. 282(2):263-270 (2002)	
	105	SELDON & GIEMBYCZ et al., "Suppression of Granulocyte/Macrophage Colony- Stimulating Factor Release from Human Monocytes by Cyclic AMP-Elevating Drugs: Role of Interleukin-10," Br. J. Pharmacol. 134(1):58-67 (2001)	
	106	SELDON et al., "Interleukin-10 Does Not Mediate the Inhibitory Effect of PDE-4 Inhibitors and Other cAMP-Elevating Drugs on Lipopolysaccharide-Induced Tumors Necrosis Factor-a Generation from Human Peripheral Blood Monocytes," Cell Biochem. Biophys. 29(1-2):179-201 (1998)	
	107	SMYTH et al., "Unlocking the Secrets of Cytotoxic Granule Proteins," J. Leukoc. Biol. 70(1):18-29 (2001)	
	108	SOMMER et al., "Therapeutic Potential of Phosphodiesterase Type 4 Inhibition in Chronic Autoimmune Demyelinating Disease," <i>Journal of Neuroimmunology</i> 79:54-61 (1997)	
	109	SOUZA et al., "Effects of Inhibition of PDE4 and TNF-α on Local and Remote Injuries Following Ischaemia and Reperfusion Injury," <i>Br. J. Pharmacol.</i> 134(5):985-994 (2001)	

Examiner Signature	/Prema Mertz/	Date Considered	04/17/2008

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Un	Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.							
Substitute	Substitute for form 1449B/PTO			Complete if Known				
INFORMATION DISCLOSURE				Application Number	10/532,291			
		Filing Date	October 21, 2003					
SIAI	STATEMENT BY APPLICANT (use as many sheets as necessary)			First Named Inventor	Rodney William Kelly			
				Group Art Unit	To Be Assigned			
		Examiner Name	To Be Assigned					
Sheet	9	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)			

Examiner	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the	T ²
Initials	No.1	item (book, magazine, journal, scrial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	1-
	110	STAFFORD & FELDMAN, "Chapter 8. Chronic Pulmonary Inflammation and Other Therapeutic Applications of PDE IV Inhibitors," Annual Reports in Medicinal Chemistry, Ed. Bristol, Academic Press, NY, USA, 31:71-80 (1996)	_
	111	STEINBRINK et al., "Induction of Dendritic Cell Maturation and Modulation of Dendritic Cell-Induced Immune Responses by Prostaglandins," Arch. Dermatol. Res. 292(9):437-445 (2000)	_
	112	STEINBRINK et al., "Induction of Tolerance by IL-10-Treated Dendritic Cells," J. Immunol. 159(10):4772-4780 (1997)	-
	113	STRASSMAN et al., "Evidence for the Involvement of Interleukin 10 in the Differential Deactivation of Murine Peritoneal Macrophages by Prostaglandin E ₂ ," J. Exp. Med. 180:2365-2370 (1994)	-
	114	TEIXEIRA et al., "Phosphodiesterase (PDE)4 Inhibitors: Anti-Inflammatory Drugs of the Future?" Trends Pharmacol. Sci. 18:164-171 (1997)	-
	115	UNDERWOOD et al., "The Influence of Endogenous Catecholamines on the Inhibitory Effects of Rolipram Against Early- and Late-Phase Response to Antigen in the Guinea Pig," Journal of Pharmacology and Experimental Therapeutics 280(1):210-219 (1997)	1
	116	VAN DER POUW KRAAN et al., "Prostaglandin-E2 Is a Potent Inhibitor of Human Interleukin 12 Production," <i>J. Exp. Med.</i> 181(2):775-779 (1995)	,
	117	VAN DER POUW KRAAN et al., "Regulation of IL-12 Production by Human Monocytes and the Influence of Prostaglandin E ₂ ," Annals of the New York Academy of Sciences 795:147-157 (1996)	1
	118	WANG et al., "Phosphodiesterase 4B2 Is The Predominant Phosphodiesterase Species and Undergoes Differential Regulation of Gene Expression in Human Monocytes and Neutrophils," Mol. Pharmacol. 56(1):170-174 (1997)	/
	119	WONG et al., "Human GM-CSF: Molecular Cloning of the Complementary DNA and Purification of the Natural and Recombinant Proteins," Science 228(4701):810-815 (1985)	-
	120	ZEINEDDINE et al., "Macrophages that Kill Glioma Cells Expressing the Membrane Form of Macrophage Colony Stimulating Factor Are Resistant to Prostaglandin E2 and Interleukin-10," Immunol. Lett. 70(1):6-36 (1999)	,

LS	ignature		TI TOTTA INOTAL	Considered	04/11/2000
-	EXAMINER:	: Initial if reference of	onsidered, whether or not citation i	is in conformance with MPEP 609.	Draw line through citation if not
ir	conformance	e and not considered.	Include copy of this form with nex	ct communication to applicant.	

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

/Prema Mertz/

Examiner

Date

04/17/2008

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute	Substitute for form 1449A/PTO			Complete if Known		
INFORMATION DISCLOSURE			OSLIDE	Application Number	10/532,291	
STATEMENT BY APPLICANT		Filling Date	October 21, 2003			
SIAI	STATEMENT BY APPLICANT (use as many sheets as necessary)			First Named Inventor	Rodney William Kelly	
ı				Art Unit	To Be Assigned	
1				Examiner Name	To Be Assigned	
Sheet	1	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)	

	U.S. PATENT DOCUMENTS							
Examiner Initials	Cite No.1	U.S. Patent Document Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
		Number - Kana Code (y known)	1					
	1	US-4,034,087	07/05/1977	Voorhees				
	2	US-4,127,612	11/28/1978	Kluender et al.				
4	3	US-5,229,496	07/20/1993	Decley et al.				
	4	US-5,391,485	02/21/1995	Deeley et al.	.			
-	5	US-5,393,870	02/28/1995	Deeley et al.				
	6	US-5,602,007	02/11/1997	Dunn et al.				
	7 .	US-5,891,432	04/06/1999	Hoo .				
	8	US-5,908,829	06/01/1999	Kelly				
	9	US-6,010,905	01/04/2000	Cohen et al.				
	10	US-6,127,378	10/03/2000	Gutterer				
	11	US-6,280,718 B1	08/28/2001	Kaufman et al.	-			
	12	US-6,458,585 B1	10/01/2002	Vachula et al.				
	13	US-6,458,589 B1	10/01/2002	Rambhatla et al.				

		FC	REIGN PATENT	DOCUMENTS		
Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant	
		Country Code ³ Number ⁴ (if known)	MM-DD-YYYY		Figures Appear	1,
	14	DE 100 64 991 A1	06/27/2002	Volker		X
	15	DE 24 31 558	01/23/1975	Kuehl jun ct al.		X
	16	EP 0 269 017 B1	07/29/1992	Zimmermann et al.		1
	17	EP 1 097 922 A1	05/09/2001	Maruyama et al.		
	18	EP 1 114 816 A1	07/11/2001	Maruyama et al.		
	19	EP 1 199 074 A1	04/24/2002	Moulon et al.		
	20	JP 10-29942	02/03/1998	Tadahiro et al.		X
	21	WO 00/64260	11/02/2000	Benoit et al.		
	22	WO 01/17479 A2	03/15/2001	Neal		
	23	WO 02/092064 A2	11/21/2002	Kelly		
	24	WO 91/06571	05/16/1991	Gefter et al.		
	25	WO 92/08474	05/29/1992	Kay et al.		
	26	WO 94/24281	10/27/1994	Garman et al.		
	27	WO 96/30022	10/03/1996	Desai et al.		
	28	WO 99/12563	03/18/1999	Berzofsky et al.		

Examiner Signature	/Prema Mertz/	Date Considered	04/17/2008

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant toujection of the property of the pr

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449B/PTO 10/532,291 INFORMATION DISCLOSURE Application Number Filing Date October 21, 2003 STATEMENT BY APPLICANT Rodney William Kelly First Named Inventor (use as many sheets as necessary) To Be Assigned Group Art Unit To Be Assigned Examiner Name 9 2 of Attorney Docket Number 20747/280 (ARDBW/P29385US) Sheet

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, scrail, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where publisher.	T ²		
	29	"Leukine®," Package Insert, Approved Text (February 1998)			
	30	ALGHAFEER & SIGAL, "Rheumatic Manifestations of Gastrointestinal Diseases," Bulletin on the Rheumatic Diseases 51(2):1-7 (Retrieved from the internet at http://www.arthritis.org/research/bulletin/vol51no2/51_2 printable.asp) (March 10, 2005)	-50		
- x	31	ASANUMA et al., "Successful Treatment of Interstitial Pneumonia with Lipo-PGE1 and Pentoxifylline in a Patient with Dermatomyositis," <i>Ryumachi</i> 37(5):719-726 (1997) (English language abstract only)	0		
	32	ASSEMAN et al., "Interleukin 10 is a Growth Factor for a Population of Regulatory T Cells," Gut 42(2):157-158 (1998)			
	33	AlTKEN et al., "Significance of Intracellular Calcium and Cyclic Adenosine 3',5'-monophosphate in the Mechanisms by Which Prostaglandins Influence Human Sperm Function," J. Reprod. Fert. 77:451-462 (1986)			
	34	BELL, J., "Transplantation: Privileged Beginnings," Nature Reviews Immunology 2:75 (2002)			
	35	BERENDS et al., "Inhibitions of PAF-Induced Expression of CD11b and Shedding of L-Selectin on Human Neutrophils and Eosinophils by the Type IV Selective PDE Inhibitor, Rolipram," Eur. Respir. J. 10:1000-1007 (1997)			
	36	BRAUN et al., "Cholera Toxin Suppresses Interleukin (IL)-12 Production and IL-12 Receptor β1 and β2 Chain Expression," <i>J. Exp. Med.</i> 189(3):541-552 (1999)			
	37	BRODSKY et al., "Forskolin Induces U937 Cell Line Differentiation as a Result of a Sustained cAMP Elevation," Eur. J. Pharmacol. 350(1):121-127 (1998)			
	38	BUCHSEL et al., "Granulocyte Macrophage Colony-Stimulating Factor: Current Practice and Novel Approaches," Clin. J. Oncol. Nurs. 6(4):198-205 (2002)			
	39	BUG et al., "cAMP Analogues Downregulate the Expression of Granulocyte Macrophage Colony-Stimulating Factor (GM-CSF) in Human Bone Marrow Stromal Cells In Vitro," Mediators of Inflammation 7:195-1999 (1998)			
	40	BURZYN et al., "Decrease in cAMP Levels Modulates Adhesion to Fibronectin and Immunostimulatory Ability of Human Dendritic Cells," <i>J. Leukoc. Biol.</i> 72:93-100 (2002)			

		P	1
Examiner		Date	04/17/2008
Signature .	/Prema Mertz/	Considered	04/17/2008

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
887272.1.

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known		
INFORMATION DISCLOSURE			OCUDE	Application Number	10/532,291	
STATEMENT BY APPLICANT		Filing Date	October 21, 2003			
		First Named Inventor	Rodney William Kelly			
	(use as many shee	u as necesso	(ערש	Group Art Unit	To Be Assigned	
				Examiner Name	To Be Assigned	
Sheet	3	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)	

	_	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	41	CANTRELL et al., "Cloning, Sequence, and Expression of a Human Granulocyte/Macrophage Colony-Stimulating Factor," <i>Proc. Natl. Acad. Sci. USA</i> 82(18):6250-6254 (1985)	
	42	CLAESSEN et al., "Reversal of Mucosal Tolerance by Subcutaneous Administration of Interleukin-12 at the Site of Attempted Sensitization," <i>Immunology</i> 88(3):363-367 (1996)	
	43	CROCKER et al., "Phosphodiesterase Type 4 Inhibitors, But Not Glucocorticoids, Are More Potent in Suppression of Cytokine Secretion by Mononuclear Cells from Atopic Than Nonatopic Donors," J. Allergy Clin. Immunol. 102(5):797-804 (1998)	
	44	DIECKGRAEFE & KORZENIK, "Treatment of Active Crohn's Disease with Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor," The Lancet 360:1478-1480 (2002)	
	45	DONCKIER et al., "IL-12 Prevents Neonatal Induction of Transplantation Tolerance in Mice," Eur. J. Immunol. 28(4):1426-1430 (1998)	
	46	DOUSA, T.P., "Cyclic-3', 5'-Nucleotide Phosphodiesterase Isozymes in Cell Biology and Pathophysiology of the Kidney," Kidney International 55:29-62 (1999)	
	47	DRUKKER et al., "Characterization of the Expression of MHC Proteins in Human Embryonic Stem Cells," <i>Proc. Natl. Acad. Sci. USA</i> 99(15):9864-9869 (2002)	
	48	DUNN et al., "IL-15 Regulation in Human Endometrial Stromal Cells," J. Clin. Endocrinol. Metab. 87(4):1898-1901 (2002)	
	49	ESCOFIER et al., "Effects of Interleukin-10 and Modulators of Cyclic AMP Formation on Endotoxin-Induced Inflammation in Rat Lung," Fundam. Clin. Pharmacol. 13(1):96-101 (1999)	-
-	50	GASPAR ELSAS et al., "Murine Myeloid Progenitor Responses to GM-CSF and Eosinophil Precursor Responses to IL-5 Represent Distinct Targets for Downmodulation by Prostaglandin E ₂ " Br. J. Pharmacol. 130(6):1362-1368 (2000)	
	51	GENBANK ACCESSION NO. NM_000758 (2002)	
	52	GOERDT et al., "Other Functions, Other Genes: Alternative Activation of Antigen- Presenting Cells," <i>Immunity</i> 10.137-142 (1999)	

Signature /Prema Mertz/ Considered	Examiner Signature	/Prema Mertz/	Date Considered	04/17/2008
------------------------------------	-----------------------	---------------	--------------------	------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
887273.1

04/17/2008

Approved for use through 10/31/2002. OMB 6651-0051
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond on a collection of information tunked is recommandate and OMB Committee a Substitute for form 1449B/PTO Complete if Known 10/532.291 Application Number INFORMATION DISCLOSURE Filing Date October 21, 2003 STATEMENT BY APPLICANT Rodney William Kelly First Named Inventor (use as many sheets as necessary) Group Art Unit To Be Assigned To Be Assigned Examiner Name Cheet of 9 Attorney Docket Number 20747/280 (ARDBW/P29385US)

	- au	OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	lackude name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), data, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	53	GROUX et al., "Interleukin-10 Induces a Long-Term Antigen-Specific Anergic State in Human CD4* T Cells," <i>J. Exp. Med.</i> 184:19-29 (1996)	
	54	GROUX et al., "A CD4' T-Cell Subset Inhibits Antigen-Specific T-Cell Responses and Prevents Colitis," Nature 389:737-742 (1997)	
	55	HAMILTON, J.A., "GM-CSF in Inflammation and Autoimmunity," Trends Immunol. 23(8):403-408 (2002)	
	56	HANCOCK et al., "Recombinant Granulocyte-Macrophage Colony-Stimulating Factor Down-Regulates Expression of IL-2 Receptor on Human Mononuclear Phagocytes by Induction of Prostaglandine," J. Immunol. 140(9):3021-3025 (1988)	
	57	HANIFIN & CHAN, "Monocyte Phosphodiesterase Abnormalities and Dysregulation of Lymphocyte Function in Atopic Dermatitis," <i>J. Invest. Dermatol.</i> 105:84S-88S (1995)	
	58	HANIFIN et al., "Type 4 Phosphodiesterase Inhibitors Have Clinical and In Vitro Anti- Inflammatory Effects in Atopic Dermatitis," Journal of Investigative Dermatology 107:51-56 (1996)	
	59	HARIZI et al., "Cyclooxygenase-2-Issued Prostaglandin E ₂ Enhances the Production of Endogenous IL-10, Which Down-Regulates Dendritic Cell Functions," <i>J. Immunol.</i> 168(5):2255-2263 (2002)	
	60	HASKÓ et al., "Suppression of IL-12 Production by Phosphodiesterase Inhibition in Murine Endotoxemia is IL-10 Independent," Eur. J. Immunol. 28:468-472 (1998)	
	61	HATA et al., "Granulysin Blocks Replication of Varicella-Zoster Virus and Triggers Apoptosis of Infected Cells," Viral Immunol. 14(2):125-133 (2001)	
	62	HAYASHIDA et al., "Antiinflammatory Effects of Colforsin Daropate Hydrochloride, a Novel Water-Soluble Forskolin Derivative," <i>Ann. Thoracic Surgery</i> 71:1931-1938 (2001)	
	63	HOLT et al., "MHC Class II Antigen-Bearing Dendritic Cells in Pulmonary Tissues of the Rat," J. Exp. Med. 167:262-274 (1988)	
	64	ICHIMURA et al., "Differentiation of a Cell Line of Human Cervical Argyrophil Small Cell Carcinoma to Macrophage Lineage Cells," Jpn. J. Cancer Res. 90:523-529 (1999)	

- 1	Signature	// TGHIQ WIGHZ/	Considered	
	*EXAMIN	ER: Initial if reference considered, whether or not citation is in confe	rmance with MPEP 609. Dr	aw line through citation if not
	in conforma	nce and not considered. Include copy of this form with next commu	nication to applicant.	

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

(Drama Maria)

Date

Examiner

PTO/SB/08B (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

UI	der the raperwork Redu	chon Aci	of 1993, no persons	are required to respond to a confection	for information unless it contains a valid OMB control number	
Substitute	for form 1449B/PTO			Complete if Known		
INFO	RMATION I	nsc1	OSUBE	Application Number	10/532,291	
	EMENT BY			Filing Date	October 21, 2003	
SIAI				First Named Inventor	Rodney William Kelly	
	(use as many sheets a	s necessa	לנח	Group Art Unit	To Be Assigned	
				Examiner Name	To Be Assigned	
Sheet	5	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)	

Examiner	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the	T ²
Initials	No.1	item (book, magazine, journal, serial, symposium, catalog, etc.)., date, page(s), volume-issue number(s), publisher, city and/or country where published.	T*.
	65	KALIŃSKI et al., "Dendritic Cells, Obtained from Peripheral Blood Precursors in the Presence of PGE ₂ , Promote Th2 Responses," Adv. Exp. Med. Biol. 416:363-367 (1997)	
	66	KALINSKI et al., "Final Maturation of Dendritic Cells Is Associated with Impaired Responsiveness to IFN-y and to Bacterial IL-12 Inducers: Decreased Ability of Mature Dendritic Cells to Produce IL-12 During the Interaction with Th Cells," <i>J. Immunol.</i> 162:3231-3236 (1999)	
	67	KALINSKI et al., "Prostaglandin E ₂ Induces the Final Maturation of IL-12-Deficient CDIa" CD83" Dendritic Cells: The Levels of IL-12 Are Determined During the Final Dendritic Cell Maturation and Are Resistant to Further Modulation," J. Immunol. 161:2804-2809 (1998)	
	68	KAMBAYASHI et al., "Cyclic Nucleotide Phosphodiesterase Type IV Participates in the Regulation of IL-10 and in the Subsequent Inhibition of TNF-a and IL-6 Release by Endotoxin-Stimulated Macrophages," Journal of Immunology 155:4909-4916 (1995)	
	69	KANAMORI et al., "Migration of Neutrophils from Blood to Tissue: Alteration of Modulatory Effects of Prostanoid on Superoxide Generation in Rabbits and Humans," Life Science 60(16):1407-1417 (1997)	
	70	KANDA & WATANABE, "Ganglioside GD1a Enhances Immunoglobulin Production by Human Peripheral Blood Mononuclear Cells," <i>Exp. Hematol.</i> 28(6):672-679 (2000)	
	71	KELLY & CRITCHLEY, "Immunomodulation by Human Seminal Plasma: A Benefit for Spermatozoon and Pathogen?" <i>Human Reproduction</i> 12(10):220-2207 (1997)	
	72	KELLY et al., "Inflammatory Mediators and Endometrial Function—Focus on the Perivascular Cell," J. Reprod. Immunol. 57(1-2):81-93 (2002)	
	73	KELLY, J., "Shooting for the Moon: Bolstered By a New Research Agenda, Parkinson's Disease Researchers Aim High," Neurology Reviews.com 9(7):1-10 (2001)	
	74	KELLY et al., "The Immunosuppressive Contribution of Prostaglandin Components of Human Semen and Their Ability to Elevate Cyclic Adenosine Monophosphate Levels in Peripheral Blood Mononuclear Cells," J. Reprod. Immunol. 26:31-40 (1994)	
	75	KOELMAN et al., "Correlation Between Oral Sex and a Low Incidence of Preeclampsia: A Role for Soluble HLA in Seminal Fluid?" J. Reproductive Immunol. 46:155-166 (2000)	

Examiner		Date	0.4147/2000
Signature	/Prema Mertz/	Considered	04/17/2008

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute	for form 1449B/PTO		-	Complete if Known		
INFO	RMATION D	ngci	OSTIRE	Application Number	10/532,291	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	October 21, 2003	
SIAI				First Named Inventor	Rodney William Kelly	
- 1	(use as many sheets a	s necessa	אמ	Group Art Unit	To Be Assigned	
				Examiner Name	To Be Assigned	
Sheet	6	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, seral, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or county where publisher.	T²
	76	KRENSKY, A.M., "A Novel Antimicrobial Peptide of Cytolytic T Lymphocytes and Natural Killer Cells," <i>Biochem. Pharmacol.</i> 59(4):317-320 (2000)	
4	77	LECHNER et al., "Nestin-Positive Progenitor Cells Derived from Adult Human Pancreatic Islets of Langerhans Contain Side Population (SP) Cells Defined by Expression of the ABCG2 (BCRP1) ATP-Binding Cassette Transporter," Biochem. Biophys. Res. Comm. 293:670-674 (2002)	
	78	LEE et al., "Isolation of cDNA for a Human Granulocyte-Macrophage Colony- Stimulating Factor by Functional Expression in Mammalian Cells," <i>Proc. Natl. Acad. Sci.</i> USA 82:4360-4364 (1985)	
	79	LOUIS et al., "Decrease in Systemic Tolerance to Fed Ovalbumin in Indomethacin- Treated Mice," International Archives of Allergy and Immunology 109(1):21-26 (1996)	
	80	MAIER et al., "Unique Molecular Surface Features of in vivo Tolerized T Cells," Proc. Natl. Acad. Sci. USA 95:4499-4503 (1998)	
	81	MAURANO et al., "Intranasal Administration of One Alpha Gliadin Can Downregulate the Immune Response to Whole Gliadin in Mice," Scand. J. Immunol. 53:290-295 (2001)	
	82	MIYATAKE et al., "Structure of the Chromosomal Gene for Granulocyte-Macrophage Colony Stimulating Factor: Comparison of the Mouse and Human Genes," <i>EMBO J.</i> 4(10):2561-2568 (1985)	
	83	MORIUCHI et al., "Synergistic Inhibition of Pannus Tissue Development In Vitro by PGE1 Plus Phosphodiesterase 4 Inhibitors," Arthritis and Rheumatism 41(9):S161 (1998)	
	84	MÜLLER et al., "IL-12 as Mediator and Adjuvant for the Induction of Contact Sensitivity In Vivo," J. Immunol. 155(10):4661-4668 (1995)	
	85	MÜLLER et al., "Subtypes of the Type 4 cAMP Phosphodiesterases: Structure, Regulation and Selective Inhibition," Trends Pharmacol. Sci. 17:294-298 (1996)	
	86	NÉMETH et al., "Amrinone and Theophylline Differentially Regulate Cytokine and Nitric Oxide Production in Endotoxemic Mice," Shock 7(5):371-375 (1997)	
	87	NEWBERRY et al., "Cyclooxygenase-2-Dependent Arachidonic Acid Metabolites Are Essential Modulators of the Intestinal Immune Response to Dietary Antigen," <i>Nature Medicine</i> 5(8):900-906 (1999)	

Examiner		Date	
Signature	/Proma Morty/	Considered	04/17/2008

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

R872273.1

P1USB08B (10-1)
Approved for use through 1031/2002. OMB 6051-003
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unclear tecesiate a valid OMB control number.

Substitut	Substitute for form 1449B/PTO			Complete if Known	
INFO	RMATION I	DISC	OSURE	Application Number	10/532,291
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Filing Date	October 21, 2003
SIA				First Named Inventor	Rodney William Kelly
				Group Art Unit	To Be Assigned
			Examiner Name	To Be Assigned	
Sheet	7	of	9	Attorney Docket Number 20747/280 (ARDBW/P29385US)	
Silect	<u> </u>	0.	<u> </u>	Attorney Docker Humber	20/47/280 (ARDBW/P29385US)

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPTIAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	88	NEWBERRY et al., "Spontaneous and Continuous Cyclooxygenase-2-Dependent Prostaglandin E, Production by Stromal Cells in the Murine Small Intestine Lamina Propria: Directing the Tone of the Intestinal Immune Response," <i>J. Immunol.</i> 166(7):4465-4472 (2001)	
	89	NINNEMANN, J.L., "Monocytes and Macrophages," in Prostaglandins, Leukotrienes, and the Immune Response, Chapter 3, pp.34-52 (1988)	
	90	OCHOA et al., "T-Cell Release of Granulysin Contributes to Host Defense in Leprosy," Nature Medicine 7(2):174-179 (2001)	
	91	PALFREYMAN & SOUNESS, "Phosphodiesterase Type IV Inhibitors," Progress in Medicinal Chemistry 33:1-52 (1996)	
	92	PFENDLER & KAWASE et al., "The Potential of Stem Cells," Obstetrical & Gynecology Survey 58(3):197-208 (2003)	
	93	PIQUET-PELLORCE et al., "Prostaglandin E ₂ Potentiates Granulocyte-Macrophage Colony Stimulating Factor-Induced Histamine Synthesis in Bone Marrow Cells: Role of cAMP," <i>Life Sciences</i> 48(25):2377-2385 (1991)	-
	94	RIESER et al., "Prostaglandin E2 and Tumor Necrosis Factor α Cooperate to Activate Human Dendritic Cells: Synergistic Activation of Interleukin 12 Production," <i>J. Exp. Med.</i> 186(9):1603-1608 (1997)	-
	95	RITZ et al., "On the Generation of Allergic Airway Diseases: From GM-CSF to Kyoto," Trends Immunol. 23(8):396-402 (2002)	
	96	ROBERTSON & SHARKEY, "The Role of Semen in Induction of Maternal Immune Tolerance to Pregnancy," Seminars in Immunology 13:243-254 (2001)	
	97	ROBERTSON et al., "Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF) Targets Myeloid Leukocytes in the Uterus During the Post-Mating Inflammatory Response in Mice," J. Reproductive Immunology 46:131-154 (2000)	
	98	ROWE et al., "Inability of Histamine to Regulate TNF-α Production by Human Alveolar Macrophages," Am. J. Respir. Cell Mol. Biol. 17:218-226 (1997)	
	99	ROZENGURT et al., "Mitogenic Effect of Prostaglandin E ₁ in Swiss 3T3 Cells: Role of Cyclic AMP," Journal of Cellular Physiology 116:379-384 (1983)	

Examiner	/Prema Mertz/	Date	7
Signature		Considered	04/17/2008

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. R872273.1

Ur	der the Paperwork Redu	ction Act	of 1995, no persons	are required to respond to a collection	of information unless it contains a valid OMB control number.	
Substitute	for form 1449B/PTO			Complete if Known		
INFO	RMATION I	oisci	OSURE	Application Number	10/532,291	
	EMENT BY			Filing Date	October 21, 2003	
SIA				First Named Inventor	Rodney William Kelly	
1	(use as many sheets o	is necessa	(עיני	Group Art Unit	To Be Assigned	
				Examiner Name	To Be Assigned	
Sheet	8	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)	

	_	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, sproposium, catalog, etc.), date, paget(a), volume-issue number(t6), publisher, city and/or country where published.	T ²
	100	RUGTVEIT et al., "Differential Distribution of B7.1 (CD80) and B7.2 (CD86) Costimulatory Molecules on Mucosal Macrophage Subsets in Human Inflammatory Bowel Disease (IBD)," Clin. Exp. Immunol. 110(1):104-113(1997)	
	101	SALMI & JALKANEN et al., "Human Leukocyte Subpopulations from Inflamed Gut Bind to Joint Vasculature Using Distinct Sets of Adhesion Molecules," <i>Journal of Immunology</i> 166(7):4650-4657 (2001)	
	102	SANTAMARIA et al., "Rolipram Inhibits Staphylococcal Enterotoxin B-Mediated Induction of the Human Skin-Homing Receptor on T Lymphocytes," J. Invest. Dermatol. 113:82-89 (1999)	
	103	SCHEUER et al., "Interference with Tolerance Induction in Vivo by Inhibitors of Prostaglandin Synthesis," Cellular Immunology 104(2):409-418 (1987)	
	104	SCHWACHA et al., "Cyclooxygenase 2-Mediated Suppression of Macrophage Interleukin-12 Production After Thermal Injury," Am. J. Physiol. Cell Physiol. 282(2):263-270 (2002)	
	105	SELDON & GIEMBYCZ et al., "Suppression of Granulocyte/Macrophage Colony- Stimulating Factor Release from Human Monocytes by Cyclic AMP-Elevating Drugs: Role of Interleukin-10," Br. J. Pharmacol. 134(1):58-67 (2001)	
	106	SELDON et al., "Interleukin-10 Does Not Mediate the Inhibitory Effect of PDE-4 Inhibitors and Other cAMP-Elevating Drugs on Lipopolysaccharide-Induced Tumors Necrosis Factor-a Generation from Human Peripheral Blood Monocytes," Cell Biochem. Biophys. 29(1-2):179-201 (1998)	
	107	SMYTH et al., "Unlocking the Secrets of Cytotoxic Granule Proteins," J. Leukoc. Biol. 70(1):18-29 (2001)	
-	108	SOMMER et al., "Therapeutic Potential of Phosphodiesterase Type 4 Inhibition in Chronic Autoimmune Demyelinating Disease," Journal of Neuroimmunology 79:54-61 (1997)	
	109	SOUZA et al., "Effects of Inhibition of PDE4 and TNF-α on Local and Remote Injuries Following Ischaemia and Reperfusion Injury," Br. J. Pharmacol. 134(5):985-994 (2001)	

Examiner Signature	. /Prema Mertz/	Date Considered	04/17/2008

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (tute as many sheets as necessary)				Complete if Known		
				Application Number	10/532,291	
				Filling Date	October 21, 2003	
				First Named Inventor	Rodney William Kelly	
				Group Art Unit	To Be Assigned	
				Examiner Name	To Be Assigned	
Sheet	9	of	9	Attorney Docket Number	20747/280 (ARDBW/P29385US)	

	-		
Examiner Initials	No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, seral, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	110	STAFFORD & FELDMAN, "Chapter 8. Chronic Pulmonary Inflammation and Other Therapeutic Applications of PDE IV Inhibitors," Annual Reports in Medicinal Chemistry, Ed. Bristol, Academic Press, NY, USA, 31:71-80 (1996)	
	111	STEINBRINK et al., "Induction of Dendritic Cell Maturation and Modulation of Dendritic Cell-Induced Immune Responses by Prostaglandins," Arch. Dermatol. Res. 292(9):437-445 (2000)	
	112	STEINBRINK et al., "Induction of Tolerance by IL-10-Treated Dendritic Cells," J. Immunol. 159(10):4772-4780 (1997)	
	113	STRASSMAN et al., "Evidence for the Involvement of Interleukin 10 in the Differential Deactivation of Murine Peritoneal Macrophages by Prostaglandin E ₂ ," J. Exp. Med. 180:2365-2370 (1994)	
	114	TEIXEIRA et al., "Phosphodiesterase (PDE)4 Inhibitors: Anti-Inflammatory Drugs of the Future?" Trends Pharmacol. Sci. 18:164-171 (1997)	
	115	UNDERWOOD et al., "The Influence of Endogenous Catecholamines on the Inhibitory Effects of Rolipram Against Early- and Late-Phase Response to Antigen in the Guinea Fig," Journal of Pharmacology and Experimental Therapeutics 280(1):210-219 (1997)	
	116	VAN DER POUW KRAAN et al., "Prostaglandin-E2 Is a Potent Inhibitor of Human Interleukin 12 Production," <i>J. Exp. Med.</i> 181(2):775-779 (1995)	
	117	VAN DER POUW KRAAN et al., "Regulation of IL-12 Production by Human Monocytes and the Influence of Prostaglandin E ₂ ," Annals of the New York Academy of Sciences 795:147-157 (1996)	
	118	WANG et al., "Phosphodiesterase 4B2 Is The Predominant Phosphodiesterase Species and Undergoes Differential Regulation of Gene Expression in Human Monocytes and Neutrophils," Mol. Pharmacol. 56(1):170-174 (1997)	
	119	WONG et al., "Human GM-CSF: Molecular Cloning of the Complementary DNA and Purification of the Natural and Recombinant Proteins," Science 228(4701):810-815 (1985)	
	120	ZEINEDDINE et al., "Macrophages that Kill Glioma Cells Expressing the Membrane Form of Macrophage Colony Stimulating Factor Are Resistant to Prostaglandin E2 and Interleukin-10," Immunol. Lett. 70(1):63-68 (1999)	

Examiner Signature	/Prema Mertz/	Date Considered	04/17/2008			
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.